



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 146

[Docket No. FDA-2023-N-2632]

Food Standards of Identity Modernization; Pasteurized Orange Juice; Request for Information

AGENCY: Food and Drug Administration, Department of Health and Human Services.

ACTION: Petition for rulemaking; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that the Florida Citrus Processors Association (FCPA) and Florida Citrus Mutual (FCM) have filed a citizen petition requesting that we amend the standard of identity (SOI) for pasteurized orange juice (POJ) by adjusting the minimum soluble solids content from 10.5° to 10° Brix. We are issuing this document to request comments, data, and information about the issues presented in the petition.

DATES: Submit either electronic or written comments and scientific data and information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-2632 for "Food Standards of Identity Modernization; Pasteurized Orange Juice; Request for Information." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly

viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:
<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Vivien Yan Peng, Center for Food Safety and Applied Nutrition, Office of Nutrition and Food Labeling (HFS-800), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371; or Philip L. Chao,

Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. FCPA and FCM Petition

The SOI for POJ requires that the product contains not less than 10.5 percent by weight of orange juice soluble solids (also expressed as degree Brix), exclusive of the solids of any added optional sweetening ingredients, and the ratio of the Brix hydrometer reading to the grams of anhydrous citric acid per 100 milliliters of juice is not less than 10 to 1 (§ 146.140(a) (21 CFR 146.140(a)). The Brix level expresses the percentage of orange juice solids present in a product. The SOI for POJ allows for the addition of concentrated orange juice ingredients and certain optional sweetening ingredients to adjust the Brix (§ 146.140(b) and (c)), provided that the label of POJ bears a statement that the concentrated orange juice ingredient or optional sweetening ingredient has been added (§ 146.140(e)(1) and (2)). Under this standard, the “optional sweetening ingredients” (or “sweeteners”) are sugar, invert sugar, dextrose, dried corn sirup, and dried glucose sirup (§ 146.140(c)).

The FCPA and FCM jointly submitted a citizen petition (Docket No. FDA-2022-P-1668) on July 25, 2022, asking us to amend the SOI for POJ to reduce the minimum soluble solids requirement for POJ from 10.5° to 10° Brix, exclusive of the solids from any added optional sweetening ingredients. See Citizen Petition from Florida Citrus Processors Association Inc. and Florida Citrus Mutual Inc., entitled “Request to Amend Pasteurized Orange Juice Standard of Identity,” sent to the Division of Dockets Management (now called the Dockets Management Staff), Food and Drug Administration, dated July 22, 2022 (“Petition”). The FCPA and FCM stated that when FDA issued the SOI for POJ in 1963 (see “Orange Juice and Orange Juice Products; Definitions and Standards of Identity; Findings of Fact and Final Order,” 28 FR 10900, October 11, 1963), FDA recognized that Florida was the dominant supplier of juice oranges with

an average Brix of 11.8°. The petitioners asserted that, based on the fruits used in preparing POJ at that time, FDA set a minimum Brix value of 10.5° for the POJ standard (Petition at page 3).

The FCPA and FCM stated that Florida's average Brix level has steadily dropped over the past couple of decades due to a bacterial disease called "citrus greening disease," also known as Huanglongbing (*id.*). (According to information on the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service's (APHIS) website, symptoms of trees infected with citrus greening include blotchy mottle leaves, stunted growth, reduced fruit size, premature fruit drop, corky veins, and root decline, and the disease eventually causes tree death. See USDA APHIS, "Citrus Greening," at

[https://www.aphis.usda.gov/aphis/ourfocus/planthealth/plant-pest-and-disease-programs/pests-and-diseases/citrus/citrus-](https://www.aphis.usda.gov/aphis/ourfocus/planthealth/plant-pest-and-disease-programs/pests-and-diseases/citrus/citrus-greening#:~:text=Huanglongbing%20(HLB)%2C%20also%20known,when%20feeding%20on%20new%20shoots).)

[greening#:~:text=Huanglongbing%20\(HLB\)%2C%20also%20known,when%20feeding%20on%20new%20shoots\).](https://www.aphis.usda.gov/aphis/ourfocus/planthealth/plant-pest-and-disease-programs/pests-and-diseases/citrus/citrus-greening#:~:text=Huanglongbing%20(HLB)%2C%20also%20known,when%20feeding%20on%20new%20shoots).) There is no cure for citrus greening disease. The FCPA and FCM also maintained that severe weather, particularly Hurricane Irma in 2017, has resulted in reduced production of oranges and normal fruit sugar content (Petition at pages 3 to 4). The FCPA and FCM stated that, due to these factors, seasonal average Brix values (weighted by volume) are hovering below the minimum of 10.5° Brix (Petition at page 4). The FCPA and FCM stated that the POJ SOI was carefully constructed to reflect the qualities of U.S. oranges, and asserted that it should now be updated to align with the properties of the modern U.S. crop (Petition at page 5).

The FCPA and FCM noted that the POJ SOI sets specific requirements for juice content and labeling, including a minimum fruit sugar level (Petition at page 3). The FCPA and FCM stated that most fruit juices, albeit many of which have a relatively lower volume of sales, have no U.S. standards and that this regulatory discrepancy further emphasizes the need to amend the orange juice SOI to keep pace with modern scientific understanding and naturally occurring dynamics impacting product production (Petition at page 7). The FCPA and FCM asserted that without such an update, POJ products will be further disadvantaged in the market (*id.*).

The FCPA and FCM maintained that the SOIs for various orange juice products are intended to serve the interest of consumers and the POJ standard established POJ as a high-quality and minimally processed juice that is heat-treated to eliminate potentially harmful pathogens and is not concentrated or reconstituted with added water (Petition at page 3). They asserted that consumers widely understand POJ to be natural, not from concentrate juice made from mature Florida oranges (Petition at page 5), although they did not provide information demonstrating this consumer understanding.

The Petition included the results of a consumer survey to assess orange juice and consumer “willingness to buy” orange juice with varying levels of sweetness under hypothetical settings which was conducted online among a total of 1,027 adult men and women, aged 18 to 69 years old, who consume 100 percent fruit juice at least once in a typical 2-week period (Petition at Appendix 4). From this consumer survey, the FCPA and FCM concluded that 96 percent of the consumers in the study accepted the idea that a natural product, like orange juice, could have varying levels of sweetness (Petition at page 6). The FCPA and FCM also noted that 95 percent of those surveyed agreed that orange juice with less sugar should still be called orange juice, and 76 percent claimed they would have no concerns with a less sweet orange juice (id.). The petitioners did not provide information on how these general statements and preferences relate to the Brix level for POJ.

The FCPA and FCM stated that the 10° minimum Brix level they request for POJ is consistent with the minimum Brix level of 10° for the SOI for canned orange juice specified in 21 CFR 146.141 (Petition at page 6). The FCPA and FCM also asserted that the 10° Brix level would be consistent with the applicable Codex General Standard for Juices and Nectars, which has no minimum but allows for Brix for not-from-concentrate POJ to be at the Brix level of the fruit from which the juice is directly expressed (id.). They also noted that the European Fruit Juice Directive incorporates a 10° minimum Brix, established by the European Fruit Juice industry in the AIJN Code of Practice (id.). The FCPA and FCM stated that the proposed

minimum Brix decrease would help to bring the POJ standard into alignment with these international food standards (Petition at pages 6 to 7).

Finally, the FCPA and FCM maintained that a temporary marketing permit (TMP) under § 130.17 (21 CFR 130.17) for POJ with a lower Brix level would not be a viable option, due to the overwhelming presence of low-Brix orange juice crops in recent years, because it would be burdensome for manufacturers to make labeling changes and add stock keeping units for the lower-Brix products and could cause consumer confusion (Petition at page 5). No information was provided on consumer understanding.

II. Summary of the 1963 Final Order

As noted above, FDA published a final order establishing SOIs for certain orange juice products, including POJ, in 1963. The final order contained various findings of fact, including a statement that “Florida orange juices available for processing” had an approximate average Brix level of 11.8° at the time (28 FR 10900 at 10905). While the FCPA and FCM maintained that this Brix value of 11.8° was used to set the standard for POJ (Petition at page 3), we clarify that FDA recognized this value in the context of the reconstituted orange juice standard, with FDA setting a minimum Brix of 11.8° in its standard for reconstituted orange juice (28 FR 10900 at 10906). By contrast, for POJ, FDA set a minimum Brix of 10.5°, recognizing that “the juice of many legally mature oranges that come on the market would not meet [a Brix of 10.5°]” and stating that producers could add frozen single-strength juice or orange juice concentrate to achieve a higher Brix level (28 FR 10900 at 10902). On the basis of these and other facts and evidence, FDA established SOIs for orange juice and various orange juice products.

III. Request for Comments

We invite interested persons to submit comments, data, and information concerning the need for, and the appropriateness of, amending the SOI for POJ. We especially invite comment and supporting data, as appropriate, on the following matters:

1. The SOI for POJ requires that the product contains not less than 10.5 percent by weight of orange juice soluble solids (that is, the Brix level), exclusive of the solids of any added optional sweetening ingredients (§ 146.140(a)). Would amending the SOI for POJ from 10.5 to 10 percent by weight of orange juice soluble solids continue to promote honesty and fair dealing in the interest of consumers? Specifically, would such an amendment result in products that are inconsistent with consumer expectations about POJ? The petitioners noted that POJ with a lower Brix has less sugar – specifically, when Brix value is lowered from 10.5° to 10.25° or 10°, the sugar content is reduced from 18 grams to 17 grams per 8 oz of product (see Petition at Appendix 4, page 19). Would POJ products with a Brix level between 10° and 10.5° taste less sweet or have less orange flavor such that consumers would not accept them? Please explain your reasoning.
2. Below are the Nutrition Facts labels for the POJ with different Brix levels provided by the petitioners (id.). From left to right are labels for product with 10.5° Brix, 10.25° Brix, and 10.0° Brix.

Nutrition Facts

1 servings per container
Serving size 8 fl oz (246g)

Amount per serving

Calories 110

% Daily Value*

Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 24g	9%
Dietary Fiber less than 1g	4%
Total Sugars 18g	
Includes 0g Added Sugars	0%

Protein 2g

Vitamin D 0mcg	0%
Calcium 27mg	2%
Iron 0mg	0%
Potassium 455mg	10%
Vitamin C 74mg	80%
Thiamin 0.2mg	15%
Niacin 1mg	6%
Vitamin B ₆ 0.1mg	6%
Folate 96mcg DFE	25%
Magnesium 27mg	6%

*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Nutrition Facts

1 servings per container
Serving size 8 fl oz (245g)

Amount per serving

Calories 110

% Daily Value*

Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 24g	9%
Dietary Fiber less than 1g	4%
Total Sugars 17g	
Includes 0g Added Sugars	0%

Protein 2g

Vitamin D 0mcg	0%
Calcium 27mg	2%
Iron 0mg	0%
Potassium 434mg	10%
Vitamin C 73mg	80%
Thiamin 0.2mg	15%
Niacin 1mg	6%
Vitamin B ₆ 0.1mg	6%
Folate 90mcg DFE	25%
Magnesium 25mg	6%

*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Nutrition Facts

1 servings per container
Serving size 8 fl oz (245g)

Amount per serving

Calories 100

% Daily Value*

Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 22g	8%
Dietary Fiber less than 1g	4%
Total Sugars 17g	
Includes 0g Added Sugars	0%

Protein 2g

Vitamin D 0mcg	0%
Calcium 27mg	2%
Iron 0mg	0%
Potassium 419mg	8%
Vitamin C 85mg	90%
Thiamin 0.2mg	15%
Niacin 1mg	6%
Vitamin B ₆ 0.1mg	6%
Folate 89mcg DFE	20%
Magnesium 25mg	6%

*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

If the SOI for POJ is amended in the manner as requested in the petition, there may also be some nutritional changes to POJ. Specifically, the Nutrition Fact labels provided by the petitioners show that several nutrients, such as potassium, folate, and vitamin C, would change with the Brix. Would such products have lower levels of certain nutrients than POJ under the current SOI? If so, would such decreases in nutrient levels lead consumers to not accept such products? Would consumers be willing to accept POJ with differing amounts of certain nutrients? Would it depend on the specific type of nutrient? Please be specific and explain your reasoning. Would it depend on the amount the nutrient declaration was changed? Please be specific about what (if any amount) would be acceptable at either a higher or lower level of what is currently declared for POJ.

3. Orange juice that does not meet the minimum Brix of 10.5° in the SOI may, under § 146.140(a) and (b), be blended with one or more of the optional concentrated orange juice ingredients (which would be labeled as specified in § 146.140(e)(1)) or with a higher-Brix POJ to meet the 10.5° Brix minimum.
 - (a) Would the use of concentrated orange juice ingredients impact consumers' decisions to purchase or consume POJ products? What if concentrated orange juice ingredients only contribute one-fourth of the total orange juice solids in the finished product, as currently specified by the SOI (§ 146.140(b))? Do consumers expect that POJ is produced entirely from non-concentrate orange juice? Please explain your reasoning.
 - (b) Oranges from other countries and states may be used to produce POJ with a higher Brix. Would the use of orange juice from other countries or other states impact consumers' decisions to purchase or consume POJ products? Please explain your reasoning.
4. Would orange juice producers apply for a TMP under § 130.17 to market POJ with Brix levels between 10° and 10.5° in order to gather data on consumers' expectations and acceptance of POJ with Brix levels in this range? If orange producers would not apply

for such a TMP, please explain why. To satisfy the labeling provision under § 130.17(c)(9), would labeling POJ with Brix in this range as having lower Brix or lower sugar be feasible? Please explain why or why not. Is there another way that POJ with Brix between 10° and 10.5° could be labeled if it were market-tested under a TMP? If so, please explain how it could be labeled.

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

Dated: August 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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